CLAIMS

1. A physicochemically stable aqueous composition including clozapine in suspension.

2. A physicochemically stable aqueous composition according to claim 1 together with a wetting agent, wherein the pH of the composition is maintained in the range of about 6 to about 11.

3. The composition according to claim 1 or 2 wherein the pH of the composition is maintained within the range of about 6 to about 11 using a buffer system.

4. The composition according to claim 3 wherein the buffer system is a sodium phosphate/sodium hydroxide buffer system.

5. The composition according to any one of the previous claims wherein the pH is maintained in the range of from about 6 to about 8.

6. The composition according to any one of the previous claims wherein the amount of clozapine in the composition is from about 0.1% to about 10% by weight based on the total volume of the composition.

7. The composition according to any one of claims 2 to 6 wherein the wetting agent is present in an amount of between about 0.1% and about 15%.

8. The composition according to any one of claims 2 to 7 wherein the wetting agent is selected from any one or more of propylene glycol, glycerin, or polyethylene glycol.

9. The composition including according to any one of the previous claims including polyvinyl pyrrolidone (PVP).

10. The composition according to claim 9 wherein the PVP is present in an amount of between about 0.1% and 2.0% by weight based on the total volume of the composition.

11. The composition according to any one of the previous claims wherein the composition includes a suspending agent and/or a preservative.

12. The composition according to claim 11 wherein the suspending agent is present in an amount of between about 0.4% and about 2.0%.

13. The composition according to claim 11 wherein the preservative is present in an amount of between about 0.1% and about 0.5%.

14. The composition according to claims 11 or 12 wherein the suspending agent is xanthan gum.

15. The composition according to claim 11 or 13 wherein the preservative is a mixture of methyl, propyl and butyl parabens.

16. The composition according to any one of the previous claims wherein the composition further includes a sweetening agent and/or a flavouring substance.

17. The composition according to claims 1 or 2 wherein the composition includes: clozapine, glycerine, sodium dihydrogen phosphate dihydrate/NaOH buffer, xanthan gum, methyl paraben, propyl paraben, butyl paraben, and water.

18. The composition according to claim 17 wherein the composition includes PVP.

19. A method for preparing a physicochemically stable aqueous composition including clozapine in suspension, the method including the step of controlling the pH of the formulation between about 6 and about 11.

20. The method according to claim 19 wherein the pH is controlled between 6 and 8.

21. The method according to claim 19, 20 or 21 wherein the method further includes the addition of PVP.

22. A method of producing a physicochemically stable aqueous composition including clozapine in suspension including the following steps:

(a) stirring the active ingredient clozapine with about three quarters of the propylene glycol ascribed to the batch;

(b) addition of the buffer salt (and optionally sweetening agents) dissolved in about half the volume of water ascribed to the batch with constant stirring;

(c) adjusting the pH value with the base component of the buffer with mixing;

(d) addition of the preservatives dissolved in the remaining propylene glycol;

(e) slow addition of the suspending agent with continuous stirring until the mixture thickens;

(f) further diluting the suspension with water to the desired end-volume.

23. A method for producing a physicochemically stable aqueous composition including clozapine in suspension including the following steps:

(a) stirring the active ingredient clozapine with about three quarters of the glycerine ascribed to the batch;

(b) addition of the buffer salt (and optionally sweetening agents) dissolved in about half the volume of water ascribed to the batch with constant stirring;

(c) adjusting the pH value with the base component of the buffer with mixing;

(d) addition of the preservatives dissolved in a small volume of water;

(e) slow addition of the suspending agent wetted with the remaining glycerine with continuous stirring until the mixture thickens;

(f) further diluting the suspension with water to the desired end-volume.

24. The method according to claims 22 or 23 wherein PVP is added as an aqueous solution following addition of the suspending agent.

25. A composition according to claim 1 substantially as herein described with reference to any one of the Examples.

26. A method according to claim 19 substantially as herein described with reference to any one of the Examples.